

## **REMARKS**

Claims 34 through 42 are pending in the application. Applicants respectfully request consideration and withdraw of the rejection in view of the remarks below.

### **DOUBLE PATENTING REJECTION**

Claims 34-42 are rejected under the non-statutory double patenting doctrine over claims 1-3, 5-7 and 20 of US Patent 6,911,026. This rejection is respectfully traversed.

With regard to the double patenting rejection of claims 34-42, the Applicants believe the present claims are patentably distinct and not identical to the conflicting claims in the commonly owned 6,911,026 patent, which common ownership would not present possible harassment by multiple assignees. Specifically, the present claims recite "one or more optical conduits in the catheter" that are rotatable within the catheter, unlike the '026 patent claims that recite ultrasonic or laser imaging devices absent any rotation. Thus, the Applicants submit claims 34-42 are patentably distinct.

### **REJECTION UNDER 35 U.S.C. § 103**

Claims 34 - 42 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Ponzi in view of Nevo. This rejection is respectfully traversed.

With respect to claims 34, 35 and 39, these claims have been amended to clarify that the one or more magnetic members disposed in the distal end of the catheter is oriented by the *magnetic members* which align relative to the direction of an externally applied magnetic field.

The Final Office Action states on page 4 that Ponzi discloses one or more magnet members (such as 72, etc.), as recited in columns 9 and 10 in Ponzi. However, the electromagnetic sensor 72 disclosed in Ponzi is used for sensing location, and is not intended to be oriented by an externally applied magnetic field. The whole point of the

electromagnetic sensor 72 was to **sense** the location of the distal tip rather than to **move** the sensor. If the electromagnetic sensor 72 moved during an attempt to sense location using an externally applied magnetic field, any attempt to sense location of the electromagnetic sensor via an external magnetic field would be counter-productive.

While the electromagnetic sensor 72 disclosed in Ponzi could possibly be inherently responsive to magnetic fields, it is well known by one of ordinary skill that magnet attraction force falls off with the fourth power of distance and would not cause any appreciable response. Furthermore, there is no indication in Ponzi that the electromagnetic sensor 72 could inherently be oriented, or moved at all, by an externally applied magnetic field. This is inconsistent with the factual inquiries for determining obviousness set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966).

There must be evidence to reasonably support the determination that an electromagnetic sensor in the distal end of a catheter inherently would be oriented by an externally applied magnetic field. The mere fact that a certain thing could result from a given set of circumstances is not sufficient to support the determination that orientation is possible. A *prima facie* case of obviousness is established by presenting evidence that would have led one of ordinary skill in the art to employ the relevant teachings of the references to arrive at the claimed invention. *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1998). Movement of the Ponzi electromagnetic sensor, if at all possible, is not the same as orienting the distal tip, which the magnets (24, 432, 526, 618) in the present invention provide for by aligning relative to a magnetic field.

The Office Action further states that Nevo teaches the use of a magnetically controlled catheter to steer the catheter through the body. However, Nevo specifically

teaches away from the use of magnetic objects inside the body, which cannot be used with real-time MRI because of the MRI magnetic field. Rather, Nevo teaches applying a **current** in three orthogonal gradient coils in the distal end of a catheter to **generate a magnetic dipole** that interacts with an **MRI magnetic field**, which creates a torque for rotating the magnetic dipole to align relative to the MRI magnetic field direction. Thus, Nevo also fails to teach orienting the tip of a medical device having magnets that align with the direction of an applied magnetic field. It would not have been obvious to a person of ordinary skill in view of Ponzi or Nevo to use a medical device having magnets on the distal end to orient the medical device relative to the direction of an applied magnetic field, because Ponzi or Nevo teach away from the use of magnets and disclose the use of complex coils within the distal end of the medical device. As such, Applicants believe that claims 34, 35 and 39 as currently amended are not obvious in view of Ponzi or Nevo, and are patentable.

With respect to claim 35, this claim has been amended to clarify the atherectomy device comprises *magnet members* that orient the distal end to align relative to an applied magnetic field, whereby the distal end is oriented by *changing* the direction of the externally applied magnetic field to cause the magnet members to align relative to the magnetic field in a desired direction. Ponzi and Nevo both fail to teach orienting the tip of a medical device having magnets, which align with the direction of an applied magnetic field. The Applicant submits that it would not have been obvious to a person of ordinary skill in view of Ponzi or Nevo to use a medical device having magnets on the distal end, because Ponzi and Nevo disclose the use of complex coils within the distal end of the medical device. Moreover, Ponzi teaches away from the use of magnets

in an MRI magnetic field, and does not teach changing the direction of the MRI magnetic field but rather the magnetic dipole of the medical device. As such, Applicants believe that claim 35 as currently amended is not obvious in view of Ponzi or Nevo, and is patentable for at least these reasons.

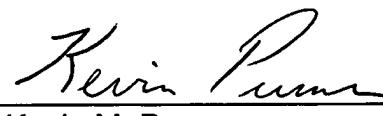
With respect to claims 36 through 38, these claims depend from claim 35, which applicants believe to be allowable as currently amended. Thus, for at least these reasons, Applicants submit that claims 36 through 38 are also in a condition for allowance.

With respect to claims 40 through 42, these claims depend from claim 39, which applicants believe to be allowable as currently amended. Thus, for at least these reasons, Applicants submit that claims 40 through 42 are also in a condition for allowance.

It is believed that all of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot by the present amendments. If it will advance the prosecution of this application, the examiner is invited to call the undersigned at (314) 726-7500.

Respectfully submitted,

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